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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,896	08/01/2003	Klaus Preissner	06478.1491	9809

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/631,896	PREISSNER ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) *4-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final action. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 8/17/2006 has been entered.

Rejections and/or objections not reiterated from the previous office action mailed 4/28/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant has added claim 13. Claims 4-12 are withdrawn as being drawn to non-elected inventions.

Newly amended claim 3 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicant has amended claim 3 to insert additional activators for plasma coagulation factor, which are each considered separate and distinct species of the invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the subject matter of claim 3 that is newly

presented (factor XII, kinogen, and prekallikrein) has been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments--Claim Rejections - 35 USC § 102

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Shimkets et al. (WO 00/58473), as evidenced by Braasch et al. (Biochemistry, Vol. 41, No. 14, 2002, pages 4503-4510), for the reasons of record set forth in the office action mailed on 4/28/2006.

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al. (US 6,248,724 B1), for the reasons of record set forth in the office action mailed on 4/28/2006. This rejection is maintained for the same reasons as the Shimkets et al. rejection above.

Applicant asserts that Shimkets et al. do not disclose that a nucleic acid or peptide-nucleic acid can enhance coagulation. The examiner is relying upon Shimkets et al. for teaching that PNAs were known inhibitory molecules, whereas Braasch et al. was relied upon for teaching that an elevated oligonucleotide dose can lead to nonselective toxicity and cell death. Therefore, any PNA of the prior art, such as the PNAs taught by Shimkets et al. or Moore et al., formulated in a pharmaceutical composition would qualify as prior art when present in a high enough concentration to induce toxicity, since toxicity is correlated to a promotion of coagulation, as instantly recited.

In absence of a teaching to draw a nexus between PNAs and increased coagulation, increased dosage of PNAs to a level of toxicity is the only possible mechanism found by the examiner to explain how a PNA would enhance coagulation, as instantly recited.

Applicant further argues that the claims further require an activator for a plasma coagulation factor. Applicant asserts that the specification defines various activators for plasma coagulation factor. Contrary to applicant's assertion, the specification does not define "activator for plasma coagulation factor", but rather discloses "a particularly suitable activator" (see page 3, paragraph 2). Since the specification does not define "activator for plasma coagulation factor", any RNA is embraced by this terminology because the specification discloses that any RNA can be a procoagulant cofactor, thereby activating plasma coagulation factor by serving as a cofactor to FSAP. Therefore, the compositions taught by Shimkets et al. and Moore et al. that comprise RNA and a PNA anticipate the instant invention.

New Objections/Rejections

Claim Objections

Claim 13 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The subject matter of claim 3 that is newly added has been withdrawn, as explained above. Therefore, claim 13 is a substantial duplicate of claim 3.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claim is drawn to a composition which comprises an activator for plasma coagulation factor and an amount, sufficient for promoting coagulation, of natural or synthetic RNA or peptide-nucleic acids.

The instant specification teaches "A particularly suitable activator is (a) factor VII activating protease (FSAP) or its proenzyme and (b) factor XII, kinogen, and prekallikrein" (see page 3, paragraph 2 of the instant specification). Therefore, the specification teaches one particularly suitable activator, but instant claim 1 is drawn to any activator for plasma coagulation factor.

The instant claim embraces a huge genus of activators of plasma coagulation factors including a large genus of proteins, as well as any RNA because the

specification discloses that any RNA can be a procoagulant cofactor, thereby activating plasma coagulation factor by serving as a cofactor to FSAP.

Although the specification discloses "a particularly suitable activator", the specification does not describe a sufficient number of activators for plasma coagulation factor to describe the instantly claimed genus of any activator for plasma coagulation factor.

Given the breadth of agents embraced in the instantly claimed genus, one could not envision the member genus of activators. Therefore, the skilled artisan would not be able to recognize that the applicant was in possession of the claimed genus at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hagen et al. (Proc. Natl. Acad. Sci., Vol. 83, 1986, pages 2412-2416).

The invention of the above claims is drawn to a composition which comprises an activator for plasma coagulation factor and an amount, sufficient for promoting coagulation, of natural or synthetic RNA or peptide-nucleic acids. The activator is further specified to be factor VII activating protease or its proenzyme.

Hagen et al. teach that factor VII is a precursor to a serine protease that is present in mammalian plasma. Hagen et al. teach clones coding for factor VII that were obtained from cDNA libraries prepared from poly(A) RNA from human liver and that factor VII is synthesized with a prepro-leader sequence (see abstract, for example). It is noted that any teaching of transcription of factor VII activating protease or its proenzyme constitutes prior art to the instant invention, which only requires for a composition to comprise either factor VII activating protease or its proenzyme in the presence of any RNA. The instant specification does not disclose what amount of RNA is "sufficient for promoting coagulation", as instantly recited. In absence of a structural characteristic defining what amount is required of the RNA, any amount of RNA is considered to be an amount sufficient for promoting coagulation.

Therefore, the instant invention is anticipated by Hagen et al., based on the teaching of the synthesis of factor VII.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHB

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER